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April 16, 1999

Mr. William K. Hubbard
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

**Re: Federal Register Request for Information: Performance Standard for *Vibrio vulnificus*
Docket Number 98P-0504, Volume 64, Number 13, Page 3300-3301**

Dear Mr. Hubbard:

The National Aquaculture Association, representing a diversity of finfish and shellfish species groups, appreciates the opportunity to comment on the Food and Drug Administration's request for information on a performance standard for *Vibrio vulnificus*. The following comments are in lieu of specific answers to your questions posed in the notice.

The Center for Science in the Public Interest petition to establish a zero-tolerance standard for *Vibrio vulnificus* in molluscs is the attempt of a special interest group to sway public health policy without the use of scientific-based information. The Interstate Shellfish Sanitation Conference (ISSC) is an appropriate forum with which the Food and Drug Administration (FDA) can address such issues of public health risk.

Use of state-of-the-art science can be valuable, and must be tempered with careful analysis of its practical implications and appropriate historical perspectives to determine public health risks. State-of-the-art science does not necessarily imply better science or science that can substantively assist FDA in its risk-based decision making. Technology that differentiates pathogenic strains from benign has yet to be developed. The capability of the patented Ameripure process does not have the data to support the claim of 100% effectiveness nor does it have the capability to differentiate strains. The FDA, therefore should not mandate the Ameripure process of the entire shellfish industry harvest without supporting evidence. This will not preclude illnesses or deaths from improper post-harvest storage procedures or from contact with the bacterium through cuts or wounds while swimming or harvesting shellfish in waters where the pathogenic bacteria are present. Until more information is gathered, a better course of action would be to pose seasonal harvest restrictions and possibly regulations mandating refrigeration of harvested shellfish from areas impacted by the bacteria.

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The ISSC developed an Interim Control Plan in 1998 for *Vibrio parahaemolyticus*, another naturally-occurring bacterium that set control measures for the industry. This plan was effective on the west coast when the industry halted sales of oysters for raw consumption. The plan calls for data collection and research to further develop a policy. Establishing standards without the substantiating data and research to develop the data would do harm to the shellfish industry and very little toward assuring public health safety. We urge the FDA to work with the ISSC to develop the data and support the research needed to properly assess the public health risk of these commonly and naturally-occurring bacteria.

Sincerely,

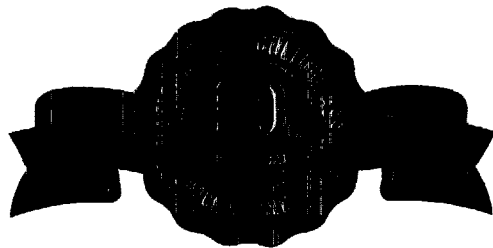
A handwritten signature in cursive script that reads "Jesse Chappell".

Jesse Chappell, Ph.D.
President

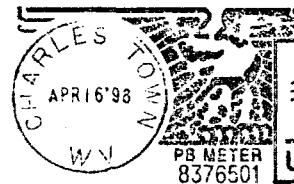
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